IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

WEST VIRGINIA DEPARTMENT OF HEALTH AND
HUMAN RESOURCES, BUREAU FOR MEDICAL
SERVICES,

Plaintiff,

v. CIVIL ACTION NO. 2:09-cv-00847

KATHLEEN SEBELIUS, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

I. Introduction

This is a lawsuit by the West Virginia Department of Health and Human Resources ("DHHR") against the Secretary of United States Department of Health and Human Services (the "Secretary") and other federal agencies for withholding Medicaid payments. The parties have filed cross motions for summary judgment. For the reasons explained below, the defendants' Motion for Summary Judgment [Docket 20] is **GRANTED**. The plaintiff's Motion [Docket 23] is **DENIED**.

II. Background

A. Statutory Framework

The Medicaid statute is located in Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq*. Medicaid is a cooperative federal-state program established "for the purpose of providing federal financial assistance to states that choose to reimburse certain costs of medical treatment for needy persons." *Harris v. McRae*, 448 U.S. 297, 301 (1980). "Although participation in the

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Medicaid program is entirely optional, once a State elects to participate, it must comply with the requirements of Title XIX." *Id.* Every state has elected to participate in the voluntary Medicaid program. Each state administers its Medicaid program pursuant to broad federal requirements and the terms of its own state Medicaid plan. 42 U.S.C. §§ 1396, 1396a. A state plan must be approved by the Secretary. Once approved, a state is generally eligible to receive federal matching funds, or "federal financial participation" ("FFP") for a percentage of the amounts "expended . . . as medical assistance under the State plan." *Id.* § 1396b(a)(1).[1]

"Medical assistance" means "payment of part or all of the cost" of certain kinds of care and services provided to individuals eligible for Medicaid assistance. *Id.* § 1396d(a). The extent of FFP in a state's Medicaid plan depends upon that state's Federal Medical Assistance Percentage ("FMAP"). FMAP is the percentage of the state's medical assistance expenditures for which federal reimbursement is available. *Id.* § 1396d(b); *see also* 42 C.F.R. § 433.10. In May 2004, West Virginia's FMAP rate was 78.14 percent, meaning that federal funds accounted for roughly seventy-eight cents of every dollar spent on Medicaid assistance in West Virginia. *See* 68 Fed. Reg. 35889, 35890 (June 17, 2003).

Title 42 U.S.C. § 1396b establishes the procedures for awarding a grant of FFP to a state's Medicaid plan. Prior to the start of a given quarter, a state provides the federal Centers for Medicare and Medicaid Services ("CMS") with an estimate of its allowable Medicaid expenditures in that quarter. 42 U.S.C. § 1396b(d)(1). CMS then pays the state in advance "the amount so estimated." *Id.* § 1396b(d)(2). Concomitantly, however, this same section requires that CMS reduce the award

[1] The Secretary has delegated responsibility for approving state plans and plan amendments to the Centers for Medicare and Medicaid Services. 42 C.F.R. §§ 430.14, 430.15.

"to the extent of any overpayment . . . which the Secretary determines was made under this section to such State for any prior quarter." *Id.* § 1396b(d)(2)(A); *Perales v. Heckler*, 611 F. Supp. 333, 335 (N.D.N.Y. 1984) ("When the Secretary finds that the state's prior quarterly estimate exceeds the amount which the state expended for allowable costs, the Secretary reduces future FFP to the state in order to adjust for the amount of the state's overestimate for any prior quarter.").

When a state discovers it has made a Medicaid overpayment, it has sixty days to attempt to recover such a payment before the Secretary adjusts "the Federal payment to such State on account of such overpayment." 42 U.S.C. § 1396b(d)(2)(C). At the end of that sixty-day period, the Secretary may adjust the payment of FFP to that state to account for the overpayment "whether or not recovery was made." *Id.* For purposes of this subsection, overpayment "means the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act." 42 C.F.R. § 433.304.

B. Facts

1. West Virginia's Settlement with Dey

On October 11, 2001, West Virginia's Attorney General filed a lawsuit against Dey, LP and other pharmaceutical manufacturers on behalf of West Virginia's Department of Health and Human Resources ("DHHR")/Bureau for Medical Services ("BMS"), Public Employees Insurance Agency ("PEIA"), and Worker's Compensation Division ("WCD"). AR 139-157.[2] That suit alleged that Dey and Warrick Pharmaceuticals had employed a fraudulent-marketing scheme for the asthma drug

[2] Citations to "AR __" refer to the administrative record filed with the court on November 20, 2009. The administrative record is found at Docket 19.

albuterol sulfate (“albuterol”). West Virginia asserted that, in an effort to increase market share, Dey and Warrick inflated the published Average Wholesale Price (“AWP”) of albuterol while simultaneously decreasing the actual sales price of the drug. Consequently, the BMS, which “relies on the AWPs published in industry compendia to determine the amount of reimbursement paid to pharmacies, physicians, and other providers for most drugs,” paid inflated prices for albuterol. *Id.* at 159. By creating a spread between providers’ actual costs and the published AWP that BMS used to reimburse purchasing providers, Dey and Warrick were able to sell more albuterol. West Virginia alleged that “for one year alone, from July, 1999 to June, 2000, Medicaid paid almost $1.7 million . . . of which almost $650,000.00 was overpaid based upon the inflated AWPs.” *Id.* at 164.

Count One of West Virginia’s complaint against Dey alleged fraud and abuse in the Medicaid Program under West Virginia Code section 9-7-6. Article 7 of Chapter Nine of the West Virginia Code is entitled “Fraud and Abuse in the Medicaid Program.” That section provides the following:

> Any . . . corporation . . . which willfully, by means of a false statement or representation, or by concealment of any material fact, or by other fraudulent scheme, devise or artifice on behalf of . . . itself, or others, obtains or attempts to obtain benefits or payments or allowances under the medical programs of the department of welfare to which . . . it is not entitled, or, in a greater amount than that to which . . . it is entitled, shall be liable to the department of welfare in an amount equal to three times the amount of such benefits, payments or allowances to which . . . it is not entitled, and [attorney fees and costs].

W. Va. Code § 9-7-6.

West Virginia maintained that Dey and the other pharmaceutical-company defendants knew “the State relied on AWPs as stated in industry sources . . . to set reimbursement amounts for drugs purchased under the Medicaid Program.” AR 173. As such, their scheme “caused the AWPs provided . . . to be inflated and false, and with the intent that these overpayments would constitute

unlawful remuneration to providers to buy Defendants' drugs in lieu of less costly alternatives" to the State. *Id.* West Virginia asserted it was "entitled to three times the amount of the overpayments," attorney fees and costs. *Id.* Counts Two through Five asserted state law claims for deceptive trade practices, fraud, and unjust enrichment.

Apparently anticipating a trial against Dey and the other pharmaceutical manufacturers, the State prepared an estimate of damages. This estimate of damages, which was said to be "most complete for Medicaid," estimated total damages attributable to Dey at $1,416,033.82. AR 241, 249. The memorandum identified the damages for each of the three State agency parties identified as follows: PEIA at $146,336.99; WCD at $317,544.25, and Medicaid at $952,152.57. *Id.* at 249. Under this calculation, the Medicaid damages equaled 67.24 percent of the total damages incurred by the various State agencies.

In May 2004, West Virginia settled its claims against Dey (the "Dey settlement"). The settlement agreement required that Dey pay West Virginia $850,000 in "full and final settlement of all allegations and claims" described by the agreement. AR 186.[3] Settled "covered conduct" included West Virginia's claims that Dey "'manipulated' the price for its drugs published by various industry compendia so that DEY could 'market the spread' between the price listed as the 'average wholesale price' in such compendia, on which STATE agencies' have chosen to base their reimbursements to pharmacies . . . and the price at which pharmacies and other providers were able to obtain DEY's drugs on the open market." *Id.* at 184. In exchange for the settlement payment, West Virginia agreed to "fully and finally release [Dey] . . . from any civil or administrative claim,

[3] The settlement agreement included an award of attorneys' fees and costs separate from this $850,000 payment.

action, suit or proceeding . . . the STATE has or may have or could assert in the future under any source of law for the Covered Conduct." *Id.* at 187. The parties' agreed order dismissed "all claims" asserted in the litigation "with prejudice as being fully compromised, settled, and agreed." *Id.* at 207. The State divided the settlement proceeds between the PEIA, which received $750,000 and the Consumer Protection Fund of the State of West Virginia, which received the remaining $100,000. *Id.* at 239.

2. Disallowance by CMS

Four years later, in May 2007, CMS learned of the Dey settlement. AR 237. On November 23, 2007, CMS determined that a portion of the Dey settlement constituted a Medicaid overpayment. CMS subsequently issued a disallowance for $634,525 against the DHHR. *Id.* at 19-21.[4] CMS later revised the disallowance calculation to reflect the portion of the settlement amount allocable to the WCD and PEIA, resulting in a revised disallowance of $446,607. *Id.* at 108. CMS calculated this revised disallowance by multiplying the $850,000 Dey settlement amount by the share of the State's estimated damages allocable to Medicaid (67.2408 percent). This yielded $571,546.80. CMS then multiplied $571,546.80 by West Virginia's FMAP rate of 78.14 percent. This equaled $446,607.

C. Procedural History

1. Proceedings before the DAB

West Virginia appealed CMS's disallowance to the Department of Health and Human Service's Departmental Appeals Board (the "DAB" or the "Board"). West Virginia presented five arguments in its administrative appeal: (1) the allocation of settlement proceeds to DHHR was

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[4] The initial disallowance was calculated by applying West Virginia's FMAP rate of 74.65 percent against the entire $850,000 settlement. AR 19.

arbitrary; (2) 42 U.S.C. § 1396b(d)(2) did not authorize the disallowance; (3) West Virginia had no duty to recoup from Dey; (4) in the absence of a duty to recoup, CMS could not allocate to DHHR settlement dollars that it did not receive; and (5) under the facts and circumstances of the case the disallowance was inequitable. Although West Virginia challenged CMS's calculation methods, it offered no alternative.

On May 26, 2009, the DAB affirmed the disallowance. AR 1-15. The Board observed that this case presented the same issues that the Board had decided in a prior disallowance appeal filed by the West Virginia DHHR. AR 8-9 (citing *W. Va. Dept. of Health and Human Resources*, DAB No. 2185 (2008) (ruling that federal government was entitled to share of settlement proceeds from suit against oxycodone manufacturer)). The Board determined that CMS had likewise properly decided that the federal government was entitled to a share of the Dey settlement, and that CMS had properly calculated that share to be sixty-seven percent.

2. District Court Proceedings

On July 24, 2009, West Virginia filed a complaint seeking judicial review of the DAB's decision. The Complaint presents a bevy of challenges to the Board's ruling. Some were presented to the Board on administrative appeal; some were not.

The arguments presented to the Board were as follows: that the disallowance is not statutorily authorized, that West Virginia was under no duty to recoup the settlement amounts and consequently is not liable for failing to do so, that the allocation of 67 percent of the settlement proceeds to DHHR is arbitrary, and that the disallowance is inequitable because of the time that passed between the date of the settlement and the issuance of the disallowance.

West Virginia also raises arguments that were not presented to the Board: that CMS misapplied the definition of "provider" in 42 C.F.R. § 433.304, that the disallowance action constitutes a new substantive rule for which prior notice-and-comment rule making is required, that CMS did not comply with the Regulatory Flexibility Act, that the disallowance is inconsistent with OMB Circular A-87, that the disallowance decision was not supported by substantial evidence, and that the disallowance contravenes the federal Constitution in several respects.

III. Standard of Review

The Administrative Procedure Act, 5 U.S.C. § 701 *et seq* (the "APA") constrains the court's scope of review. Under the APA, a reviewing court shall set aside agency actions, findings of fact, and conclusions of law that are "arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law." 5 U.S.C. § 706(2)(A). The APA further provides that a court shall set aside agency actions "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" along with actions that are "without observance of procedure required by law." *Id.* § 706(2)(C)-(D).

The Fourth Circuit has explained that "[a]gencies are ordinarily permitted to choose in adjudication among permissible meanings of statutes they are charged with administering, without spelling out their interpretations beforehand through notice-and-comment rulemaking." *West Virginia v. Thompson*, 475 F.3d 204, 210 (4th Cir. 2007). Furthermore, the court of appeals has recognized that "[t]he Medicaid Statute is a prototypical 'complex and highly technical regulatory program' benefitting from expert administration, which makes deference particularly warranted." *Id.* at 212 (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). Consequently,

the Secretary's interpretation of the Medicaid Statute should be reviewed "through the lens of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)." *Id.* Applying *Chevron* deference means that if a "statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Young v. Community Nutrition Inst.*, 476 U.S. 974 (1986). In such a circumstance, "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Id.*

IV. Discussion

A. West Virginia has waived its arguments that were not presented to the DAB.

The first issue is whether West Virginia has waived any of its arguments because they were not first presented to the Board. The defendants argue that West Virginia has waived all of these arguments. West Virginia insists that it has not. As explained below, the court agrees with the defendants.

In reviewing an administrative-agency decision, a court should not consider arguments that were not raised before the agency. This is particularly true when the issue raised would require fact-finding by the agency and in cases where "the Secretary's expertise is relevant" to a resolution of the issue. *Pleasant Valley Hosp., Inc. v. Shalala*, 32 F.3d 67, 70 (4th Cir. 1994); *see also Delta Foundation, Inc. v. United States*, 303 F.3d 551, 560 (5th Cir. 2002) ("The rationale for requiring issue exhaustion is that parties should have an opportunity to offer evidence before the administrative agency charged with the fact finding responsibility."). The Fourth Circuit has explained that "[a]s a general matter, it is inappropriate for courts reviewing appeals of agency

decisions to consider arguments not raised before the administrative agency involved." *Pleasant Valley Hosp.*, 32 F.3d at 70. This rule, the court of appeals recognized, is prudential rather than jurisdictional. *Id.*

West Virginia contends that these issues are not actually being raised for the first time in this court. Rather, it argues that it is merely presenting a new line of reasoning on an exhausted issue. This argument lacks merit. The point of exhaustion is to allow an administrative agency, which has expertise in the issues involved, a chance to pass judgment. Indeed, the Supreme Court has explained that

> [a] reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented and deprives the [agency] of an opportunity to consider the matter, make its ruling, and state the reasons for its action.

Unemployment Compensation Comm. v. Aragon, 329 U.S. 143, 155 (1946).

West Virginia is seeking to have this court consider issues not raised before the DAB. The court declines this invitation. West Virginia's new arguments present issues on which the Secretary's expertise would be relevant and they should have been presented to the Board before the State raised them in this court.[5] The court therefore declines to hear West Virginia's claims that CMS misapplied the definition of "provider" in 42 C.F.R. § 433.304, that the disallowance action constitutes a new substantive rule for which prior notice-and-comment rule making is required, that CMS did not comply with the Regulatory Flexibility Act, that the disallowance is inconsistent with OMB Circular A-87, that the disallowance decision was not supported by substantial evidence.

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[5] Even if West Virginia has not waived these arguments, the court has considered them and concludes that they are without merit.

The court also declines to hear West Virginia's constitutional claims. Constitutional arguments, like statutory arguments, are subject to exhaustion requirements in administrative proceedings. *See Volvo GM Heavy Truck Corp. v. U.S. Dep't of Labor*, 118 F.3d 205, 215 (4th Cir. 1997) ("The Fourth Circuit has recognized that exhaustion can be useful even where a constitutional issue is presented."); *Thetford Properties IV Ltd. P'Ship v. U.S. Dep't of Housing and Urban Dev.*, 907 F.2d 445, 448 (4th Cir. 1990). This is so because, among other reasons, a fully-developed factual record from an administrative proceeding is often critical to a court's resolution of a constitutional challenge. *See Volvo GM*, 118 F.3d at 215. West Virginia's constitutional challenges—based on anti-commandeering and intergovernmental-tax-immunity principles—depend on factual predicates regarding the manner in which overpayments are refunded to the federal government and the nature of the funds being refunded that would benefit from development during the administrative process. West Virginia failed to present these arguments to the DAB; that failure precludes the State from presenting those issues here.

B. The DAB's decision was not arbitrary, capricious, an abuse of discretion, or contrary to law.

The Medicaid Act does not permit states to be reimbursed for medical expenditures that are not medical assistance. The Act requires the Secretary to adjust payments to states in light of prior overpayments made by the federal government to the state, 42 U.S.C. § 1396b(d)(2)(A), or by the state to others (e.g., service providers, suppliers, beneficiaries) and to adjust payments to states on account of an overpayment after giving the state sixty days to attempt to recover it, at which time the Secretary shall adjust the payment "whether or not recovery was made," *id.* § 1396b(d)(2)(C).

The statutory language places the responsibility of determining the amount of an overpayment on the Secretary. 42 U.S.C. § 1396b(3)(A) ("The pro rata share to which the United States is equitably entitled, *as determined by the Secretary*, of the net amount recovered during any quarter by the State or any political subdivision thereof with respect to medical assistance furnished under the State plan shall be considered an overpayment . . . .") (emphasis added). Federal regulations provide that an overpayment by a state is "the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act." 42 C.F.R. § 433.304.

The Secretary possesses authority to withhold funds when she determines that a state made an overpayment. 42 U.S.C. § 1396b(d)(2)(C); *Dep't of Social Serv., Div of Family Serv. v. Bowen*, 804 F.2d 1035, 1041 (8th Cir. 1986); *see also Perales*, 762 F.2d at 226 (2d Cir. 1985); *Massachusetts v. Sec'y of Health and Human Serv.*, 749 F.2d 89 (1st Cir. 1984).[6] Furthermore, the Department of Health and Human Services ("HHS") may recoup the entire federal share from the state Medicaid agency even before the state makes any recovery on its own. *See* 42 U.S.C. § 1396b(d)(2)(C) (allowing withholding "whether or not recovery was made."). Therefore, CMS may

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[6] Contrary to West Virginia's claim before the DAB that it had no duty to recoup the overpayments underlying the case, § 1396b(d)(2)(C) places a clear duty on the State insofar as the State's lawsuit included claims for overpayments made by the Medicaid program to pharmacist-providers. As courts have previously held, states bear the primary burden of recovering overpayments made by their Medicaid programs. "[P]recisely because the state is in the best position to detect and prevent Medicaid fraud, it must be charged with the responsibility for its prevention. To allow the state to shift the cost of its own errors, however innocent they may be, could only lessen the efficiency of the entire program. The partnership upon which plaintiff relies does not in and of itself entitle the state to disclaim or abdicate its own obligations in order to make its own responsibilities easier to bear." *Perales*, 611 F. Supp. at 342-43.

disallow the federal share of the amount actually recovered in a settlement resolving overpayment claims.

Substantial evidence supports CMS's conclusion that the "unnecessary and excessive costs" that West Virginia paid for prescription drugs were overpayments by the State and that CMS could recover them under § 1396b(d)(2)(C). First, CMS decided the matter consistent with the allegations that the State itself pled in its amended complaint: That Dey "caused a very high number to be published as the AWP for the dosages of albuterol sulfate," AR 169, and that "[b]y maintaining the AWP at a highly inflated amount . . . Dey used third-party payors, such as Plaintiff, to overpay substantially for the drugs when they reimbursed providers for the drugs," AR 170. Second, the disallowance amount was not speculative but rather was based on actual settlement money the State received from Dey. While West Virginia dismissed the prospect that its Medicaid claims against Dey would have succeeded at trial during the proceedings before the DAB, the undisputed fact remains that West Virginia accepted settlement money to enter a binding release of those claims. HHS, which contributed approximately seventy-five cents of every dollar spent by West Virginia's Medicaid program, had a stake in recovering its share of that settlement.

Finally, while one might disagree with the Secretary's computational method, the disallowance was not arbitrary. It was calculated using the State's own damages estimates that had been prepared by the State's own representatives utilizing the State's own data and that were, by the State's own admission, "most complete for Medicaid." AR 241. Those damages estimates allocated sixty-seven percent of total damages to the Medicaid program. *Id.* Although West Virginia argued before the DAB that the damages estimates were incomplete, it failed to provide any indication the

estimates were seriously flawed or substantially overstated the alleged relative loss to Medicaid. Additionally, the State never proposed an alternate allocation method.

Furthermore, West Virginia's argument that the overpayment provisions are inapplicable to the settlement because Dey did not operate under a provider agreement with the State's Medicaid agency is meritless. The regulations define an overpayment as amounts *paid* to a provider in the first instance. But they do not say that a party settling an overpayment claim must be a provider.

West Virginia's theory in pursuing the pharmaceutical companies was built around inflated reimbursement rates that the State paid to pharmacies—which are "providers" and which West Virginia's complaint labeled as such. AR 163-64, 170 (claiming that Dey caused the State to "overpay substantially" when it "reimbursed providers for the drug"). The overpayments in this case were paid to providers pursuant to the Medicaid program. HHS is entitled to its share of those recovered overpayments regardless of the source of the recovery**.**

V. CONCLUSION

The defendants' Motion for Summary Judgment [Docket 20] is **GRANTED**. The plaintiff's Motion [Docket 23] is **DENIED**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

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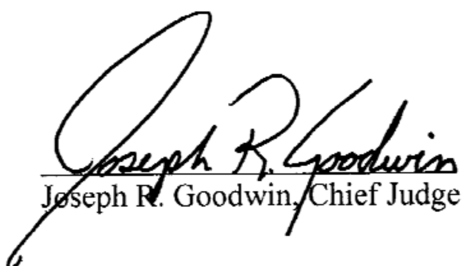

Joseph R. Goodwin, Chief Judge